

REMARKS

Claims 1-6, 8, and 9 were pending in the instant application. By this amendment, Claim 1 has been amended to present the rejected claims in form for allowance and/or appeal. In particular, Claim 1 has been amended to delete “prevention” of a neurodegenerative condition and new Claims 10-13 have been added to clarify the invention with respect to methods for treatment. Support for Claims 10-13 is found at page 6, lines 1 and 2; page 14, lines 3-14 and 21-27; page 29, lines 14-17; page 31, lines 1, 2, and 23-27; page 30, lines 4-12; page 32, lines 9-13 and 34-36; page 33, lines 27-33; and page 34, lines 1-6; As such, no new matter has been added.

Therefore, Claims 1-6, 8, 9 and 10-13 will be pending upon entry of the instant amendment.

THE REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, FOR LACK OF ENABLEMENT SHOULD BE WITHDRAWN

Claims 1-6, 8, and 9 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking enabling support in the specification. In particular, the Examiner contends that a method for the prevention of a neurodegenerative condition is not enabled because “prevention” is not a relative term, but total, and that the specification does not enable the claimed methods for preventing a neurodegenerative condition.

Applicants submit that the rejection has been overcome by the amendment to Claim 1. Although applicants respectfully disagree with the Examiner’s characterization of the definition of the term “prevention,” Claim 1 has been amended to delete methods for prevention without acquiescing to the propriety of the rejection of Claims 1-6, 8, and 9, and solely to present the rejected claims in condition for allowance and/or appeal. Applicants reserve the right to pursue claims directed to the deleted subject matter in one or more related applications.

In addition, Claims 10-13, drawn to methods for treatment of a neurodegenerative condition prior to a medical or surgical procedure, have been added. Addition of the new claims is made necessary by the amendment to Claim 1, to specify a treatment method wherein an effective non-toxic amount of erythropoietin (EPO) is administered before, rather than during or after, neurologic damage to excitable tissue occurs. Applicants submit that the new claims are disclosed and enabled by the instant application. For example, on page 14, lines 24 to 27, a method for pre-treatment of neurologic damage caused by the labor process is described wherein EPO is administered before labor. On page 30, lines 4-27, mice are administered EPO 4 hours before administration of lithium (used to induce Conditioned Taste Aversion (“CTA”)), the EPO pre-treatment was found to markedly reduce CTA caused by lithium. The results are evidence of protection from neurologic injury that effects the sense of taste. In another example, on page 31, lines 23-35, pre-treatment of mice with EPO 24 hours before administration of the neurotoxin kainate (used to induces neurologic injury causing seizure) resulted in a neuroprotective effect exemplified by delayed seizure activity. In yet another example, on page 32, lines 34-36, the ipsilateral carotoid artery was occluded by cauterization in animals as a model for ischemic focal stroke. In animals that were pre-treated with EPO prior to the cauterization procedure, the results indicate that EPO protects tissue from neurologic injury. In still another example, on page 33, lines 27-33, mice were pre-treated with EPO twenty-four hours before injury by mechanical trauma to the skull. Mice that were pre-treated with EPO exhibited some protection from brain necrosis damage. Finally, in the example on page 34, lines 3-20, mice were pre-treated with EPO before myocardium ischemic injury was induced by coronary artery ligation. EPO was again administered during the coronary artery ligation procedure used to cause the injury. The results indicate that myocardium tissue viability was maintained for longer periods of time in mice pre-treated with EPO. These methods disclosed in the specification in animal models

are also contemplated for pre-treatment of neurologic injury, *e.g.*, prevention of injury during surgical procedures, in humans as described on page 5, line 18 through page 6, line 2.

In view of the foregoing amendment, applicants submit that the rejection for lack of enablement under 35 U.S.C. §112, first paragraph, has been overcome and should be withdrawn.

CONCLUSION

Entry of the foregoing remarks and amendment into the record of the above-identified application is respectfully requested. Applicants estimate that the remarks and amendment made herein now place the pending claims in condition for allowance. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

Respectfully submitted,

Date: December 24, 2003

Laura A. Coruzzi 30,742
Laura A. Coruzzi (Reg. No.)

By: Eileen E. Falvey 46,097
Eileen E. Falvey (Reg. No.)

PENNIE & EDMONDS LLP
1155 Avenue of the Americas
New York, New York 10036-2711
(212) 790-9090

Enclosures